BIOMET

510(k) Summary

Preparation Date: April 26, 2006

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Tracy Bickel Johnson, RAC

Proprietary Name: Porous Titanium Acetabular Shells

Common Name: Acetabular shells

Classification Name: Hip joint, Metal/Polymer/Metal, semi-constrained, porous-coated uncemented prosthesis (888.3358); Prosthesis, Hip, Semi-constrained, Metal/Polymer, Cemented (888.3350); Hip joint metal/polymer constrained cemented or uncemented prosthesis (888.3310); Hip joint metal/ceramic/polymer semi-constrained cemented or non porous uncemented prosthesis (888.3353)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Hedrocel® Revision Shells (K001759), Hedrocel® Acetabular Cages (K983837)

Device Description: Porous Titanium Acetabular Shells are intended for use in reconstruction of the hip joint due to disease, deformity, or trauma. The devices are intended for general use in skeletally mature individuals undergoing primary and/or secondary revision surgery. The device is a single use implant.

This submission includes acetabular shells for use as reconstructive components. The acetabular shells range in size (OD) from 52mm to 80mm in 2mm increments. The shell is constructed of a porous titanium alloy (Ti-6Al-4V) and has been designed for cemented or non-cemented use with the option of using screws for added fixation to the native bone. The wall of the shell is composed entirely of the porous material. The rim of the implant is solid titanium for reinforcement and provides the mating geometry necessary to mate with the instrumentation. The acetabular shells are designed for use with commercially available all polyethylene acetabular liners. These polyethylene liners are to be cemented into the acetabular shells.

Intended Use:
Please note that the indications for the compatible product listing have not been changed and/or modified for this submission.

The Porous Titanium Acetabular Shells are indicated for cemented or non-cemented use in total hip replacement in cases of:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty.

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510(k) Summary – Porous Titanium Acetabular Shells
Biomet Manufacturing Corp.

Specific indications for compatible components (femorals, heads, liners, and screws) that can be used with the Regenerex™ Hip Products include:

Freedom® Constrained Liners (K030047)
The Biomet Freedom® Constrained liner is indicated for use as a component of a total hip prosthesis in primary and/or revision patients at high risk of hip dislocation due to history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered.

Tri-Polar System (K991990)
Indication #5 (Revision of previously failed total hip arthroplasty) is further specified to include recurrent dislocation.

OSS/Salvage Systems/Total Femur (K974558, K002757, K021380, K033871)
Salvage/Oncology Hip and Total Femur components are also indicated for cases of ligament deficiency, tumor resection, trauma and revision of unsuccessful osteotomy or arthrodesis.

Interlocking Stems (K990830, K042774)
Interlocking hip stems are indicated for non-cemented application in cases of revision, trauma, fracture, oncology or other situations where severe proximal bone loss may compromise the fixation and stability of a standard type hip replacement prosthesis.

HA PMI Hip Femoral Stems (K030048)
Non-cemented use for skeletally mature patients undergoing primary hip replacement surgery as a result of non-inflammatory degenerative joint disease.

Gross Hip Femoral (K001580) and Bohn Hip Femoral (K000262)
These femoral components are also indicated for treatment in conjunction with tumor resection and trauma.

Taper 2™ Porous Femoral (K050441) and Balance Microplasty (K050251)
Indication #5 (Revision of previously failed total hip arthroplasty) is not applicable for these components. These stems are indicated for the revision of previously failed femoral head resurfacing component.

Color Buffed Femoral (K992903), CB DDH Femoral (K012019), Bi-Metric Hip (K992058), CB Answer Femoral (K991987), Reach Femoral (K982367)
Indication #5 (Revision of previously failed total hip arthroplasty) instead reads, "Revisions of hip replacement components".

150mm Bi-Metric Hip Stem (K983710)
Indication #5 (Revision of previously failed total hip arthroplasty) is not applicable for these components. They are not indicated for revision procedures.

Zirconia Ceramic Heads (K964431 and K991708)
Indication #4 (Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques) is not applicable to these Zirconia Ceramic Heads.

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Biomet Manufacturing Corp.

Biolox® *delta* Ceramic Heads (K042091), Rx90™ Standard/Lateralized Femoral (K023085), Portrait Femoral (K010560), Mallory/Head Smooth Femoral (K994007), Generation 4 Polished Femoral (K031734), Modular Reach Femoral (K994038),
Indication #5 (Revision of previously failed total hip arthroplasty) instead reads, "Revision procedures where other treatment or devices have failed".

Medallion Modular Hip System (K041850)
Same list of five indications but cleared for uncemented use only.

Summary of Technologies: The technological characteristics (material modification, design, sizing, indications) of the Porous Titanium Acetabular Shells are similar to or identical to the predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2006

Biomet Manufacturing Corp.
c/o Ms. Tracy Bickel Johnson, RAC
Manager, Regulatory Affairs
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K052996
Trade/Device Name: Porous Titanium Acetabular Shells
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, JDI, KWZ, MEH, MAY
Dated: April 17, 2006
Received: April 18, 2006

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson for
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052996

Device Name: Porous Titanium Acetabular Shells

Indications for Use:

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1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
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4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
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Interlocking Stems (K990830, K042774)
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Prescription Use ___X___ AND/OR Over-The-Counter Use___No___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mm

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

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Porous Titanium Acetabular Shells
K052996
Indications for Use

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Medallion Modular Hip System (K041850)
Same list of five indications but cleared for uncemented use only.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052996